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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,807

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Bernard Fromenty

125649

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03/25/2010

Oliff & Berridge, PLC

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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

03/25/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/553,807	Applicant(s) FROMENTY ET AL.	
	Examiner GREGG POLANSKY	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-9,15-19,22-24,37-41 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,8,9,15-19 and 37-41 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 11/04/2009, to the Office Action mailed 8/11/2009 is acknowledged. Applicants amended claims and presented arguments in response to the Office Action.
2. Claims 1, 3, 8, 9, 15-19, 37-41 and 43 are presently under consideration.
3. Applicants' arguments have been fully considered and are deemed to be persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

4. Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1, 3, 8, 9, 15-19, and 38-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent Claims 1, 3, 8, and 9 are drawn to methods “for reducing the accumulation of triglycerides in tissues and blood”, “of treatment for lowering the blood levels of triglycerides”, “for treating or reducing the risk of developing obesity”, and “of treatment for reducing or reducing the risk of gaining body fat”, respectively, “comprising at least the step of **administering to a human or non human animal in need thereof**, as a therapeutically active agent, an effective amount of β -aminoisobutyric acid...” (emphasis added).

The phrase “administering to a human or non human animal in need thereof” can be interpreted to mean administering (β -aminoisobutyric acid) to a human or non human animal in need of the treatment recited in the claims' preamble. However, the phrase can also be interpreted to mean administering (β -aminoisobutyric acid) to a human or non human animal in need of administration for any reason. Thus, the claims do not clearly and concisely claim the subject matter which Applicants regard as their invention.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 8, 9, 15-19, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claims recite “ β -aminoisobutyric acid ... or an ester thereof”. There is insufficient written basis for esters of β -aminoisobutyric acid, other than C₁-C₁₀ lower alkyl esters, in the Specification.

Regarding the requirement for adequate written description of chemical entities, Applicant’s attention is directed to MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, “not a mere wish or plan for obtaining the claimed chemical invention.” *Elli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office (“PTO”) Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 “Written Description” Requirement (“Guidelines”), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,” including, *inter alia*, “functional characteristics when coupled with a known or disclosed correlation between function and structure...” *Enzo Biochem*,

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Inc. v. Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Elli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

The instant Specification discloses that "[t]he terminal carboxylic group of β -aminoisobutyric acid may be in particular under the form of an ester, for example lower alkyl ester, (in particular in C₁-C₁₀) or of an amide." See page 7, first paragraph. The Specification fails to disclose any additional teaching or examples for esters of β -aminoisobutyric acid. There is no disclosure of a precise definition of what Applicants envisage as β -aminoisobutyric acid esters useful in the instant invention.

While various lower alkyl and phenyl esters of β -aminoisobutyric acid are known in the prior art, none have been shown to be useful for the practice of Applicants' invention. Further, Applicants have not disclosed any structural characteristics or physical properties of β -aminoisobutyric acid esters from which one skilled in the art may utilize for determining which esters of β -aminoisobutyric acid are likely to be useful in the practice of Applicants' invention

Thus, Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties of esters of β -aminoisobutyric acid, aside from an exemplary discloser of C₁-C₁₀ lower alkyl esters. As such, it is not apparent that Applicant was actually in possession of, and intended to use within the context of the present invention, any specific esters of β -aminoisobutyric acid, other than C₁-C₁₀ lower

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alkyl esters, at the time the present invention was made. The skilled artisan could not “immediately envisage” the claimed compounds based on the description in the disclosure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 8, 9, 15, 16, and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs (U.S. Patent No. 4,453,941).

Jacobs teaches a method for “imparting a rich, dark color to hair or skin” comprising administering to human hair or skin a composition comprising *inter alia* β -aminoisobutyric acid. See column 6, claim 6.

As discussed above, the phrase “administering to a human or non human animal in need thereof” can be interpreted to mean administering (β -aminoisobutyric acid) to a human or non human animal in need of the treatment recited in the claims' preamble, or, the phrase can be interpreted to mean administering (β -aminoisobutyric acid) to a human or non human animal in need of administration for any reason. Therefore, if the 2nd interpretation is assumed, the teaching of Jacobs anticipates the instant claims.

Instant Claims 38-41 depend from independent Claims 1, 3, 8, and 9 respectively and thus include the limitations of the independent claims. Esters of β -aminoisobutyric

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acid are optional in the independent claims and the dependent claims do not require the use of esters of the independent claims. Therefore, the use of esters of β -aminoisobutyric acid is optional for Claims 38-41 and thus, Claims 38-41 are properly rejected.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3, 8, 9, 15-19, and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs (*supra*) as applied above.

Claims 16-19 limit Claim 1 to the treatment of an agricultural animal, a domestic animal, or a laboratory animal respectively.

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Jacobs teaches treatment of humans. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the methods of Jacobs on non-human animals. For example, the artisan would have found it obvious to use the methods of Jacobs to change the hair color of a domestic animal for the novelty of having a pet with a uniquely colored coat. Jacobs does not explicitly or implicitly disclose anything which would have influenced one of ordinary skill in the art not to use the disclosed methods on non-human animals and have a reasonable expectation of success.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. Claims 1, 3, 8, 9, 15-19, and 37-41 are rejected.
14. No claims are allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614